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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,898	04/30/2001	Ronald J. Kolata	102863-2	4070

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/845,898

Applicant(s)

KOLATA ET AL.

Examiner

Anu Ramana

Art Unit

3751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 16-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 16-36 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 11/18/02 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

*Election/Restrictions*

This application contains claims directed to the following patentably distinct species of the claimed invention:

- Species I: Figures 1-4c
- Species II: Figures 5-7B
- Species III: Figure 8

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Lisa Michaud on 1/23/03 a provisional election was made without traverse to prosecute the invention of Species I: claims 1-15 and 37 Affirmation of this election must be made by the applicant in replying to this Office action. Claims 16-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Li (US 5,954,057).

Li discloses a suspension clip assembly 200 having tissue penetrating claws 206 movable between an open and closed position by actuating member 220 and a suspension strap 212 which may be a suture (flexible member), wire, web, chain or the like (col. 3, lines 31-45, Figure 16, Figure 17, col. 14, lines 45-63, and col. 15, lines 11-54).

The initial statement of intended use and all other functional implications related thereto have been considered but do not appear to impose any patentably distinguishing structure over that disclosed by Li.

The method steps of claim 37 are inherently performed during normal use of the suspension clip assembly 200 of Li.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Claims 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce (US 5,893,878) in view of Li (US 5,954,057).*

Pierce discloses a medical instrument with a body 10, a tissue grasping element 18 with two opposed tissue grasping claws or members 26 and 28, selectively movable between an open

or a closed position, and an actuating member 32 mated to body 10 and effective in moving claws 26 and 28 between the retracted and extended positions (Figure 1 and col. 4, lines 10-22).

Pierce does not disclose a flexible member having a portion secured to body 10 with one free end that is fastenable to a support.

Li teaches a suspending tissue from a bodily support structure utilizing a flexible member or strap attached to a tissue penetrating structure (col. 3, lines 31-45, Figure 4, Figure 16 and Figure 17). Li further teaches that the suspension strap can be a wire, web, chain or the like (col. 14, lines 60-67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a flexible member or strap secured to body 10 of the Pierce instrument wherein the other end of the strap may be attached to a support structure to suspend tissue grasped by instrument 10 as taught by Li. Further, the choice of the support structure would depend on how and where the grasped tissue needs to be suspended.

Regarding claim 3, Pierce discloses that handle 20 has opposed first (50) and second (52) members wherein a force applied to bring members 50 and 52 in contact with each other causes opening of claws 26 and 28 (col. 5, lines 24-33).

Regarding claim 4, Pierce discloses that the tissue grasping element 18 has claws or members 26 and 28 comprised of flexible metal and are normally in a biased open position (Figure 1). The bias of the grasping members would be selected in accordance with the application of the instrument 10 and would be a matter of obvious design choice.

Regarding claim 5, Pierce discloses that the contact member 18 can take a variety of shapes including circular wherein the shape selected depends on the intended use of the instrument 10 (col. 4, lines 27-35).

Regarding claim 7, Pierce discloses a hollow, applicator sleeve 12, slidably disposed on body 10 that selectively engages the actuating member. Pierce does not disclose that the sleeve is removable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sleeve 12 removable since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Regarding claim 8, sleeve 12 engages the tissue grasping element 18 in a proximal position (Figure 6) and engages the tissue grasping element 18 in a distal position (Figure 7).

Regarding claim 11, see discussion for claim 4.

Regarding claims 13 and 14, Li shows an embodiment of clip 10, 200 (Figure 16) wherein the flexible member 212 is disposed in bore 234 of a core member 232 (col. 15, lines 17-21) (Figures 16 and 17) to enable hanging clip 10 from a support structure.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the flexible member 212 in the inner lumen of the body of instrument 10 as taught by Li to support instrument 10 of Pierce from a support structure. Further, the actual connection of the flexible member as taught by Li to the instrument 10 of Pierce would be a matter of obvious design choice given that the flexible member is being utilized to suspend instrument 10 from a support structure.

### ***Response to Arguments***

Applicant's arguments filed on November 18, 2002, Paper No. 9, have been fully considered but are not persuasive.

Regarding pages 17-18 of the Remarks Section, in response to Applicant's argument that the Pierce device does not teach or suggest tissue penetrating claws, it is the Examiner's position that "tissue penetrating claw" as understood from Applicant's specification (page 8, para 2, lines 11-25 and page 12, lines 22-23) is any structure with points intended to penetrate or grasp tissue. The Pierce device has structure that is capable of penetrating or grasping tissue (Figure 17, col. 2, lines 49-55 and col. 5, lines 46-52)

In response to Applicant's argument that Pierce cannot be modified to include a flexible member as taught by Li, it is the Examiner's position that both Pierce and Li are directed to tissue grasping members. And to take a perfecting feature, namely a flexible member for the purpose of suspension, from one tissue grasping member and providing it on another tissue grasping member would have been an obvious modification.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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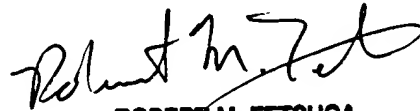
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached at (703) 308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0975.

AR

January 27, 2003



**ROBERT M. FETSUGA**  
**PRIMARY EXAMINER**